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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,144	12/21/2000	Wayne E. Cornish	01035.0025-00	2421

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ABBOTT CARDIOVASCULAR SYSTEMS INC./
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WASHINGTON, DC 20001

EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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05/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/746,144	Applicant(s) CORNISH ET AL.	
	Examiner JONATHAN ML FOREMAN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 20-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 20-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 7 and 20 - 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,325,766 to Anderson et al. in view of US Patent No.5,722,981 to Stevens.

In regard to claims 7 and 20 - 26, Anderson et al. disclose an elongated medical device having a superelastic member (12) having a first set of properties and an adjacent second section (14) having a second set of properties. The second section includes a distal end that is at least about 3 cm in length. Anderson et al. discloses using any pseudo- or super-elastic alloys or shape memory nickel-titanium alloys (Col. 2, lines 38 – 43) for the second section, but fails to disclose the alloy including an easily diffusible element consisting of oxygen or hydrogen. However, Stevens teaches a nickel-titanium alloy having a reduced superelasticity which includes oxygen or hydrogen (Col. 3, lines 41 – 47). The claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Anderson et al. and Stevens teach the use of known superelastic nickel-titanium alloys, it would have been obvious to one skilled in the art at the time of the invention to substitute one alloy for the other to achieve the predictable results of allowing the medical device to have a pre-formed shape, be stressed into another shape, and then return to its pre-formed shape.

3. Claims 7 and 22 - 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamauchi et al. ('159) in view of U.S. Patent No. 6,428,317 to Abel.

In regard to claims 7 and 22 – 26, Yamauchi et al. ('159) discloses a superelastic member having a first section (2a) with a first set of properties and an adjacent second section (2) having a second set of properties which have been altered from the first set of properties by treating the second section with an easily diffusible element (Page 5, lines 1 – 3), wherein the superelastic member comprises a nickel-titanium alloy (See Abstract). The altered properties comprise reduced superelasticity. The second section comprises a distal end having a length at least about 3 cm. However, Yamauchi et al. fail to disclose the easily diffusible element being selected from the group consisting of oxygen, hydrogen and nitrogen. However, Abel teaches that heat treatments and /or the addition of trace elements such as oxygen (O) and nitrogen (N) to nickel-titanium alloys can have very significant effects on desired superelastic properties and performance of the material (Col. 3, line 65 – Col. 4, line 14). The claims would have been obvious because the technique for improving a particular class of devices was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvements in other situations. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the member as disclosed by Yamauchi et al. to include an easily diffusible element from the group consisting of oxygen, hydrogen and nitrogen as taught by Abel in order to allow a portion the core to exhibit enhanced elastic properties.

Response to Arguments

4. Applicant's arguments filed 2/28/08 have been fully considered but they are not persuasive. The claimed invention is a product by process type claim. As such, the claimed invention is not limited to the manipulations of the recited steps, only the structure implied by the steps. MPEP

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2113. In the present case, the invention includes a first superelastic member and a second superelastic member including oxygen, hydrogen or nitrogen. In regard to the rejection of the claims over US Patent No. 6,325,766 to Anderson et al. in view of US Patent No. 5,722,981 to Stevens, Anderson et al. disclose using any pseudo- or super-elastic alloys or shape memory nickel-titanium alloys (Col. 2, lines 38 – 43) for the second section. Because Anderson et al. discloses using any pseudo- or super-elastic alloys, a reasonable expectation of success exists with the proposed modification using the alloy containing oxygen or hydrogen disclosed by Stevens. In regard to the rejection over Yamauchi et al. ('159) in view of U.S. Patent No. 6,428,317 to Abel, Abel teaches the structure (i.e. a superelastic member having oxygen, hydrogen or nitrogen) of the claimed invention. The Examiner maintains that one of ordinary skill in the art at the time of the invention to modify the member as disclosed by Yamauchi et al. to include an easily diffusible element from the group consisting of oxygen, hydrogen and nitrogen as taught by Abel in order to allow a portion the core to exhibit enhanced elastic properties.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724.

The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Samuel G. Gilbert/
Primary Examiner, Art Unit 3735